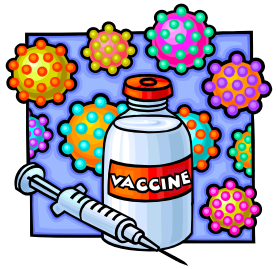


In Compliance with HB 2781, the Arizona Department of Health Services' Report on the Current National and State System for Reporting and Collecting Information Regarding Vaccine Adverse Events

To the Governor, the Speaker of the House of Representatives, the President of the Senate, and the Joint Legislative Budget Committee

March 1, 2008

Arizona Department of Health Services

Table of Contents

"Vaccination is one of the greatest public health achievements in the United States during the 20th century. Immunizations have eradicated smallpox; eliminated poliomyelitis in the Americas; and controlled measles, rubella, tetanus, diphtheria, Haemophilus influenzae type b, and other infectious diseases".*

*David Satcher, M.D., PH.D.
Assistant Secretary for Health and Surgeon General
U.S. Public Health Service
U.S. Department of Health and Human Services
Before the House Committee on Government Reform August 3, 1999

Public Health Value of Vaccines

Comparison of 20th Century Annual Morbidity and Current Morbidity, Vaccine-Preventable Diseases (pre-1990 Vaccines)

†Source: CDC. *MMWR* April 2, 1999. 48: 242-264

Numbers in green indicate at or near record lows in 2004

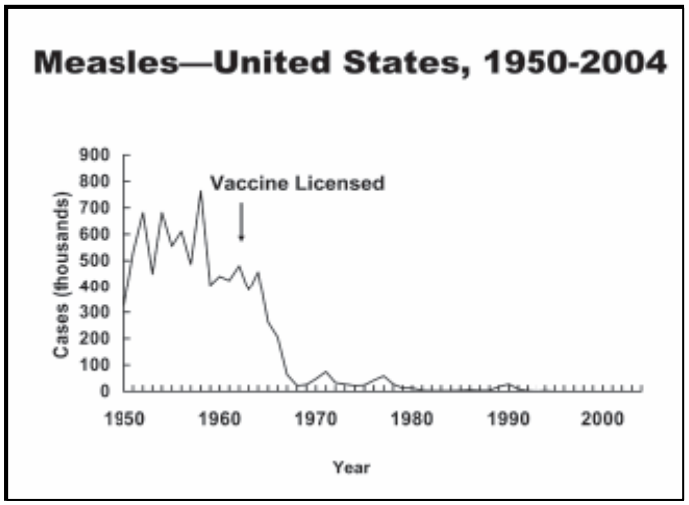
Disease	20th Century Annual Morbidity†	2004	Percent Decrease
Smallpox	48,164	0	100%
Diphtheria	175,885	0	100%
Measles	503,282	37	99.99%
Mumps	152,209	236	99.84%
Pertussis (whooping cough)	147,271	18,957	87%
Polio (paralytic)	16,316	0	100%
Rubella (German Measles)	47,745	12	99.97%
Congenital Rubella Syndrome	823	0	100%
Tetanus	1,314	27	97.95%

Comparison of Pre-Vaccine Era Estimated Annual Morbidity and Current Morbidity, Vaccine-Preventable Diseases (post-1990 Vaccines)

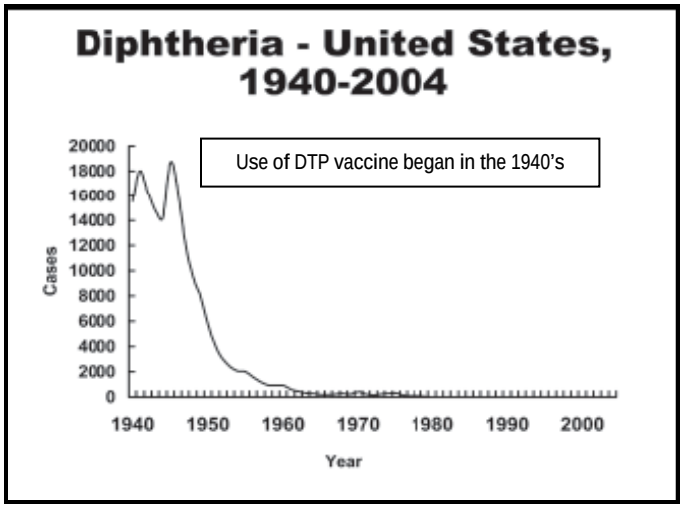
Disease	Pre-Vaccine Era Estimated Annual Morbidity	2004	Percent Decrease
Hepatitis A	117,333	32,711	72%
Hepatitis B (acute)	66,232	21,030	68%
Hib (invasive)	20,000	40	99.8%
Pneumococcus (invasive)	63,067	39,800	37%
Varicella (chicken pox)	4,085,120	817,024	80%
Influenza (<5 years)	N/A	N/A	-------
Meningococcus (invasive)	2,183	N/A	-------

*N/A – Not Available

Measles Vaccine



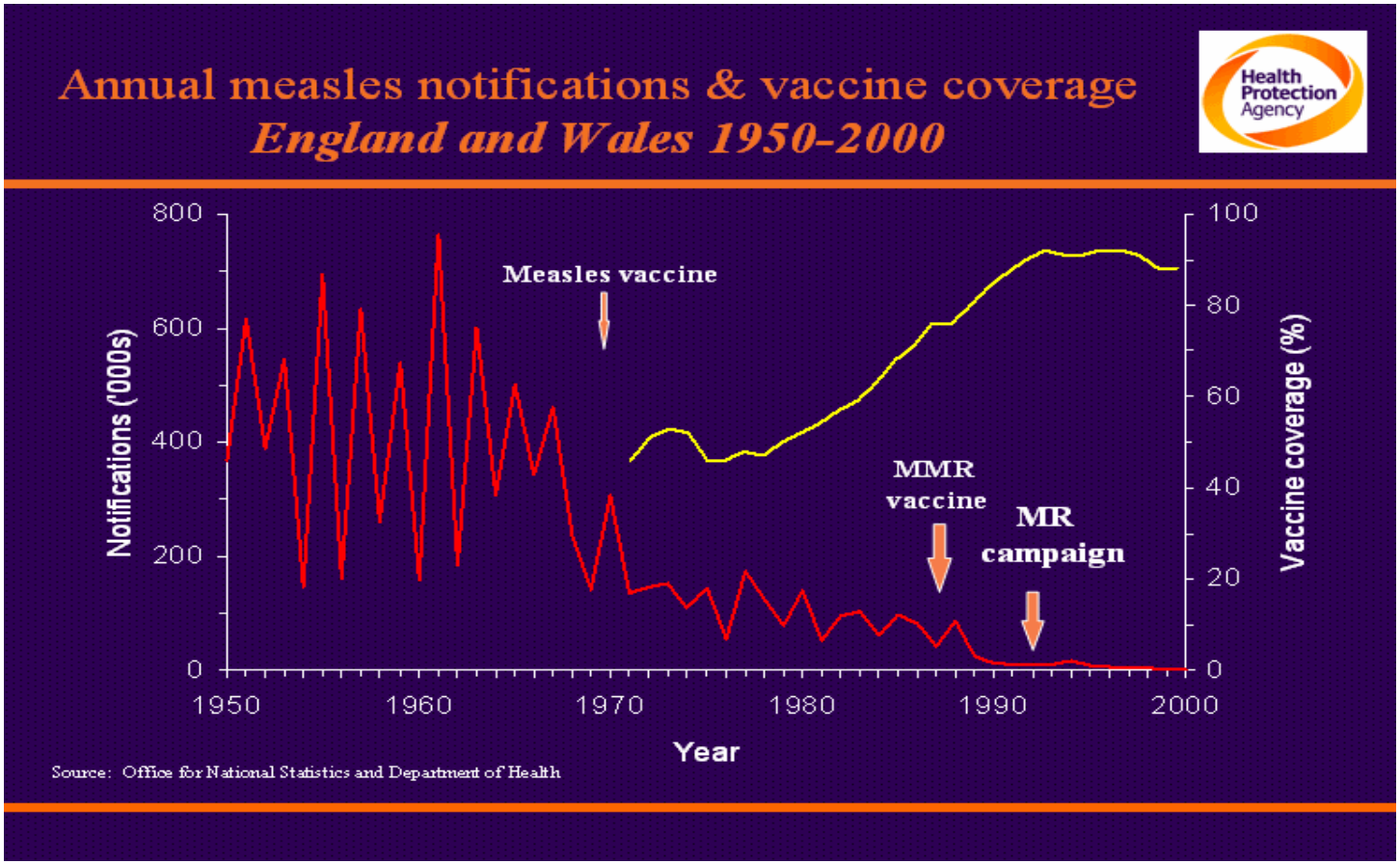
Diphtheria Vaccine



Measles* - Before 1963 (pre-vaccine), approximately 500,000 cases and 500 deaths from measles were reported annually, with epidemic cycles every 2-3 years. Following licensure of the vaccine in 1963, the incidence of measles decreased by more than 98%, and 2-3 year epidemic cycles no longer occurred. Due to unfounded concerns about the MMR vaccine, immunization coverage rates in the United Kingdom (83% whereas 95% coverage is believe to be necessary to protect the public) have decreased and the number of measles cases has dramatically increased. An all-time high number of cases was reported in the UK 2003 (438 cases) and 2004 (449 cases and one death). Arizona has had 3 cases of measles since 2000 – the last reported case was in 2005.

Diphtheria** - Diphtheria was once a major cause of morbidity (illness) and mortality (death) among children. In the 1920s in the U.S, 100,000-200,000 cases and 13,000-15,000 deaths were reported each year, gradually declining to about 19,000 cases in 1945. A more rapid decrease began with the widespread use of diphtheria toxoid in the late 1940s. From 1980 through 2004, 57 cases were reported in the U.S. (an average of 2-3 cases/year). Only 5 cases have been reported since 2000.

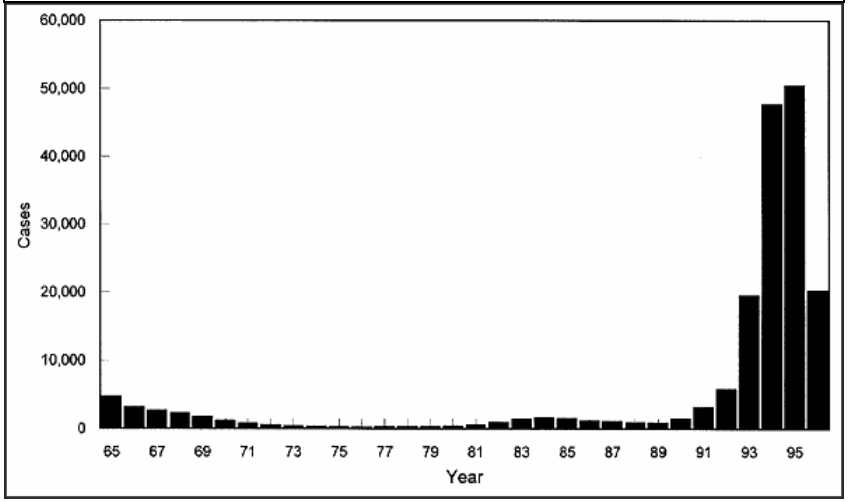
**Epidemiology and Prevention of Vaccine-Preventable Diseases 10th Edition 2007.* U.S. Department of Health and Human Services, CDC, P.134
**Ibid, P. 64



In 2006, there were 739 confirmed measles cases in England and Wales. Due to a 1998 Lancet article indicating a possible link between MMR vaccine and autism, immunization uptake of MMR among two-year-olds had declined. Between 1995 and 2001, there were 665 laboratory-confirmed cases of measles in England and Wales; by 2003, the MMR coverage level had dropped to 80% (95% coverage is considered necessary to confer herd immunity). Subsequent studies have found no link between MMR vaccine and autism.

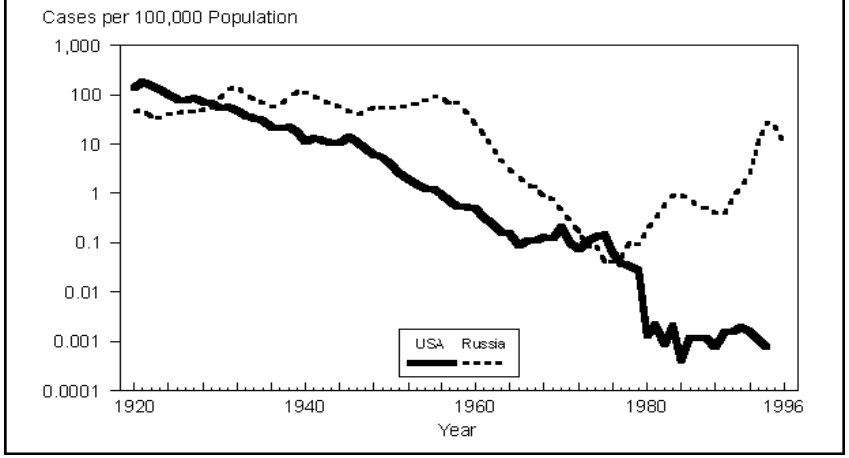
http://www.statistics.gov.uk/CCI/

Reported diphtheria cases in the Soviet Union and Newly Independent States, 1965 - 1996



In the 1990s, a massive epidemic throughout the Newly Independent States of the former Soviet Union marked the reemergence of epidemic diphtheria in industrialized countries. Diphtheria had been well controlled in the Soviet Union for more than 2 decades after universal childhood immunization was initiated in the late 1950s.
In 1993, the number of reported diphtheria cases surged to 19,462; epidemic diphtheria became established throughout urban Russia, the Ukraine, and Belarus. Russia alone reported 15,211 cases, an increase of 290% from 1992. The incidence rate in children exceeded that in adults by 60%.

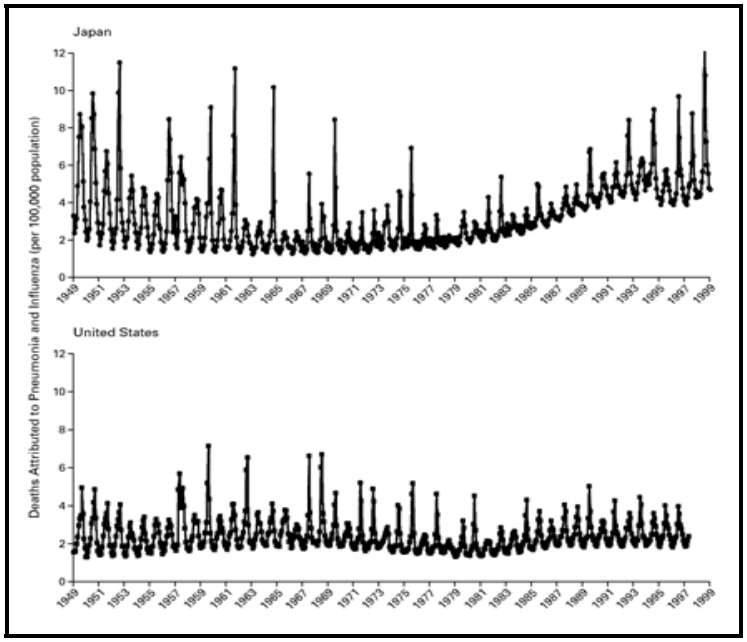
Diphtheria Incidence - United States and Russian Federation 1920 - 1996



Diphtheria incidence continued to decline steadily throughout the vaccine era in the United States and (after the immediate postwar period) in Western Europe. Cases of clinical diphtheria have become extremely uncommon; several European countries have not reported a case of diphtheria in more than 20 years

Vitek, Charles R., Wharton, Melinda. Diphtheria in the Former Soviet Union: Re-emegence of Pandemic Disease. *J Emerging Infectious Diseases*. 1998;4:539-550.

Monthly Mortality Attributed to Pneumonia and Influenza in Japan and the United States, 1949 to 1999

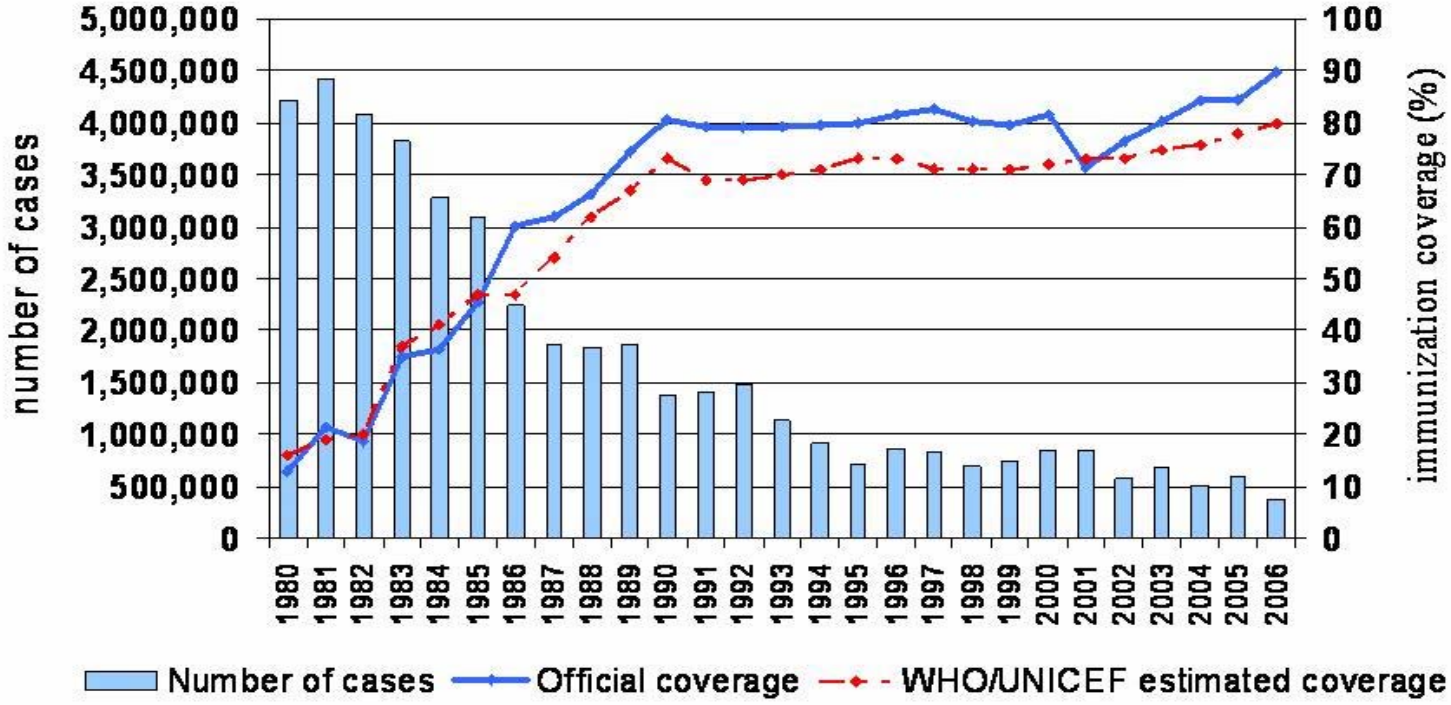


Influenza epidemics lead to increased mortality, principally among elderly persons and others at high risk, and in most developed countries, influenza-control efforts focus on the vaccination of this group. Japan, however, once based its policy for the control of influenza on the vaccination of schoolchildren. From 1962 to 1987, most Japanese schoolchildren were vaccinated against influenza. For more than a decade, vaccination was mandatory, but the laws were relaxed in 1987 and repealed in 1994; subsequently, vaccination rates dropped to low levels. When most schoolchildren were vaccinated, it is possible that herd immunity against influenza was achieved in Japan. If this was the case, both the incidence of influenza and mortality attributed to influenza should have been reduced among older persons.

With the initiation of the vaccination program for schoolchildren in Japan, excess mortality rates dropped from values three to four times those in the United States to values similar to those in the United States. The vaccination of Japanese children prevented about 37,000 to 49,000 deaths per year, or about 1 death for every 420 children vaccinated. As the vaccination of schoolchildren was discontinued, the excess mortality rates in Japan increased. *Conclusions* The effect of influenza on mortality is much greater in Japan than in the United States and can be measured about equally well in terms of deaths from all causes and deaths attributed to pneumonia or influenza. Vaccinating schoolchildren against influenza provides protection and reduces mortality from influenza among older persons.

Reichert TA, Sugaya N, Fedson DS, et al. The Japanese Experience with Vaccinating School Children Against Influenza. *NEJM* 2001 Mar 22; 344(12):889-96

Measles global annual reported incidence and MCV coverage, 1980-2006



Source: WHO/IVB database, 2007

193 WHO Member States. Data as of September 2007

Date of slide: 10 September 2007

WHO

What Would Happen If We Stopped Vaccinations?

Introduction

In the U.S., vaccines have reduced or eliminated many infectious diseases that once routinely killed or harmed many infants, children, and adults. However, the viruses and bacteria that cause vaccine-preventable disease and death still exist and can be passed on to people who are not protected by vaccines. Vaccine-preventable diseases have many social and economic costs: sick children miss school and can cause parents to lose time from work. These diseases also result in doctor's visits, hospitalizations, and even premature deaths.

Polio

Stopping vaccination against polio would people susceptible to infection with the polio virus. Polio virus causes acute paralysis that can lead to permanent physical disability and even death. Before polio vaccine was available, 13,000 to 20,000 cases of paralytic polio were reported each year in the United States. These annual epidemics of polio often left thousands of victims--mostly children--in braces, crutches, wheelchairs, and iron lungs. The effects were life-long.

In 1988, when the World Health Assembly unanimously agreed to eradicate polio worldwide, the number of cases reported globally has decreased from more than 350,000 cases in 125 countries in 1988 to 2,000 cases of polio in 17 countries in 2006. Polio remains endemic in only four countries (Afghanistan, India, Nigeria, Pakistan). To date polio has been eliminated from the Western hemisphere, and the European and Western Pacific regions. Stopping vaccination before eradication is achieved would result in a resurgence of the disease in the United States and worldwide.

Measles

Before measles vaccine was available, nearly everyone in the U.S. got measles. An average of 450 measles-associated deaths was reported each year between 1953 and 1963. In the U.S., **up to 20 percent of persons with measles are hospitalized.** Seventeen percent of measles cases have had one or more complications, such as ear infections, pneumonia, or diarrhea. Pneumonia is present in about six percent of cases and accounts for most of the measles deaths. Although less common, some persons with measles develop encephalitis (swelling of the lining of the brain) resulting in brain damage.

As many as three of every 1,000 persons with measles will die in the U.S. In the developing world, the rate is much higher, with death occurring in about one of every 100 persons with measles.

Measles is one of the most infectious diseases in the world and is frequently imported into the U.S. In the period 1997-2000, most cases were associated with international visitors or U.S. residents who were exposed to the measles virus while traveling abroad. More than 90 percent of people who are not immune will get measles if they are exposed to the virus.

According to the World Health Organization (WHO), nearly 900,000 measles-related deaths occurred among persons in developing countries in 1999. In populations that are not immune to measles, measles spreads rapidly. **If vaccinations were stopped, each year about 2.7 million measles deaths worldwide could be expected.**

In the U.S., widespread use of measles vaccine has led to a greater than 99 percent reduction in measles compared with the pre-vaccine era. If we stopped immunization, measles would increase to pre-vaccine levels.

Haemophilus Influenzae Type b (Hib) Meningitis

Before Hib vaccine became available, Hib was the most common cause of bacterial meningitis in U.S. infants and children. Before the vaccine was developed, there were approximately 20,000 invasive Hib cases annually. Approximately two-thirds of the 20,000 cases were meningitis, and one-third were other life-threatening invasive Hib diseases such as bacteria in the blood, pneumonia, or inflammation of the epiglottis.

About one of every 200 U.S. children under 5 years of age got an invasive Hib disease. **Meningitis once killed 600 children each year in the U.S. and left many survivors with deafness, seizures, or mental retardation. Since introduction of conjugate Hib vaccine in December 1987, the incidence of Hib has declined by 98 percent.**

This preventable disease was a common, devastating illness as recently as 1990; now, most pediatricians just finishing training have never seen a case. If we were to stop immunization, we would likely soon return to the pre-vaccine numbers of invasive Hib disease cases and deaths.

Pertussis (Whooping cough)

Since the early 1980s, reported pertussis cases have been increasing, with peaks every 3-4 years; however, the number of reported cases remains much lower than levels seen in the pre-vaccine era. Compared with pertussis cases in other age groups, infants who are 6 months old or younger with pertussis, experience the highest rate of hospitalization, pneumonia, seizures, encephalopathy (a degenerative disease of the brain) and death. From 1990 to 1996, 57 persons died from pertussis; 49 of these were less than six months old.

Before pertussis immunizations were available, nearly all children developed whooping cough. In the U.S., prior to pertussis immunization, between 150,000 and 260,000 cases of pertussis were reported each year, with up to 9,000 pertussis-related deaths.

Pertussis can be a severe illness, resulting in prolonged coughing spells that can last for many weeks. These spells can make it difficult for a child to eat, drink, and breathe. Because vomiting often occurs after a coughing spell, infants may lose weight and become dehydrated. In infants, **it can also cause pneumonia and lead to brain damage, seizures, and mental retardation.**

The newer pertussis vaccine (acellular or DTaP) has been available for use in the United States since 1991 and has been recommended for exclusive use since 1998. These vaccines are effective and associated with fewer mild and moderate adverse reactions when compared with the older (whole-cell DTP) vaccines.

During the 1970s, widespread concerns about the safety of the older pertussis vaccine led to a rapid fall in immunization levels in the United Kingdom. More than 100,000 cases and 36 deaths due to pertussis were reported during an epidemic in the mid 1970s. In Japan, pertussis vaccination coverage fell from 80 percent in 1974 to 20 percent in 1979. An epidemic occurred in 1979, resulted in more than 13,000 cases and 41 deaths.

Pertussis cases occur throughout the world. If we stopped pertussis immunizations in the U.S., we would experience a massive resurgence of pertussis disease. **A recent study* found that, in eight countries where immunization coverage was reduced, incidence rates of pertussis surged to 10 to 100 times the rates in countries where vaccination rates were sustained.**

*Reference for study: Gangarosa EJ, et al. Impact of anti-vaccine movements on pertussis control: the untold story. Lancet 1998;351:356-61.

Pneumococcal Disease

Before pneumococcal conjugate vaccine became available for children, pneumococcus caused 63,000 cases of invasive pneumococcal disease and 6,100 deaths in the U.S. each year. Many children who developed pneumococcal meningitis also developed long-term complications such as deafness or seizures. Since the vaccine was introduced, the incidence of invasive pneumococcal disease in children has been reduced by 75%. Pneumococcal conjugate vaccine also reduces spread of pneumococcus from children to adults. In 2003 alone, there were 30,000 fewer cases of invasive pneumococcal disease caused by strains included in the vaccine, including 20,000 fewer cases in children and adults too old to receive the vaccine. If we were to stop immunization, we would likely soon return to the pre-vaccine numbers of invasive pneumococcal disease cases and deaths.

Rubella (German Measles)

While rubella is usually mild in children and adults, up to 90 percent of infants born to mothers infected with rubella during the first trimester of pregnancy will develop **congenital rubella syndrome (CRS), resulting in heart defects, cataracts, mental retardation, and deafness.**

In 1964-1965, before rubella immunization was used routinely in the U.S., there was an epidemic of rubella that resulted in an estimated 20,000 infants born with CRS, with 2,100 neonatal deaths and 11,250 miscarriages. Of the 20,000 infants born with CRS, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded.

Due to the widespread use of rubella vaccine, only six CRS cases were provisionally reported in the U.S. in 2000. Because many developing countries do not include rubella in the childhood immunization schedule, many of these cases occurred in foreign-born adults. Since 1996, greater than 50 percent of the reported rubella cases have been among adults. Since 1999, there have been 40 pregnant women infected with rubella.

If we stopped rubella immunization, immunity to rubella would decline and rubella would once again return, resulting in pregnant women becoming infected with rubella and then giving birth to infants with CRS.

Varicella (Chickenpox)

Prior to the licensing of the chickenpox vaccine in 1995, almost all persons in the United States had suffered from chickenpox by adulthood. Each year, the virus caused an estimated 4 million cases of chickenpox, 11,000 hospitalizations, and 100-150 deaths.

A highly contagious disease, chickenpox is usually mild but can be severe in some persons. Infants, adolescents and adults, pregnant women, and immunocompromised persons are at particular risk for serious complications including secondary bacterial infections, loss of fluids (dehydration), pneumonia, and central nervous system involvement. The availability of the chickenpox vaccine and its subsequent widespread use

has had a major impact on reducing cases of chickenpox and related morbidity, hospitalizations, and deaths. In some areas, cases have decreased as much as 90% over pre-vaccination numbers.

In 2006, routine two-dose vaccination against chickenpox was recommended for all children, adolescents, and adults who do not have evidence of immunity to the disease. In addition to further reducing cases, this strategy will also decrease the risk for exposure to the virus for persons who are unable to be vaccinated because of illness or other conditions and who may develop severe disease. If vaccination against chickenpox were to stop, the disease would eventually return to pre-vaccination rates, with virtually all susceptible persons becoming infected with the virus at some point in their lives.

Hepatitis B

More than 2 billion persons worldwide have been infected with the hepatitis B virus at some time in their lives. Of these, 350 million are life-long carriers of the disease and can transmit the virus to others. **One million of these people die each year from liver disease and liver cancer.**

National studies have shown that about 12.5 million Americans have been infected with hepatitis B virus at some point in their lifetime. One and one quarter million Americans are estimated to have chronic (long-lasting) infection, of whom 20 percent to 30 percent acquired their infection in childhood. Chronic hepatitis B virus infection increases a person's risk for chronic liver disease, cirrhosis, and liver cancer. About 5,000 persons will die each year from hepatitis B-related liver disease resulting in over $700 million in medical and work loss costs.

The number of new infections per year has declined from an average of 450,000 in the 1980s to about 80,000 in 1999. The greatest decline has occurred among children and adolescents due to routine hepatitis B vaccination.

Infants and children who become infected with hepatitis B virus are at highest risk of developing lifelong infection, which often leads to death from liver disease (cirrhosis) and liver cancer. **Approximately 25 percent of children who become infected with life-long hepatitis B virus would be expected to die of related liver disease as adults.**

CDC estimates that one-third of the life-long hepatitis B virus infections in the United States resulted from infections occurring in infants and young children. About 16,000 - 20,000 hepatitis B antigen infected women give birth each year in the United States. It is estimated that 12,000 children born to hepatitis B virus infected mothers were infected each year before implementation of infant immunization programs. In addition, approximately 33,000 children (10 years of age and younger) of mothers who are not infected with hepatitis B virus were infected each year before routine recommendation of childhood hepatitis B vaccination.

Diphtheria

Diphtheria is a serious disease caused by a bacterium. This germ produces a poisonous substance or toxin which frequently causes heart and nerve problems. The case fatality rate is 5 percent to 10 percent, with higher case-fatality rates (up to 20 percent) in the very young and the elderly.

In the 1920's, diphtheria was a major cause of illness and death for children in the U.S. In 1921, a total of 206,000 cases and 15,520 deaths were reported. With vaccine development in 1923, new cases of diphtheria began to fall in the U.S., until in 2001 only two cases were reported.

Although diphtheria is rare in the U.S., it appears that the bacteria continue to get passed among people. In 1996, 10 isolates of the bacteria were obtained from persons in an American Indian community in South Dakota, none of whom had classic diphtheria disease. There was one death reported in 2003 from clinical diphtheria in a 63 year old male who had never been vaccinated.

There are high rates of susceptibility among adults. Screening tests conducted since 1977 have shown that 41 percent to 84 percent of adults 60 and over lack protective levels of circulating antitoxin against diphtheria.

Although diphtheria is rare in the U.S., it is still a threat. Diphtheria is common in other parts of the world and with the increase in international travel, **diphtheria and other infectious diseases are only a plane ride away.** If we stopped immunization, the U.S. might experience a situation similar to the Newly Independent States of the former Soviet Union. With the breakdown of the public health services in this area, diphtheria epidemics began in 1990, fueled primarily by persons who were not properly vaccinated. More than 150,000 cases and 5,000 deaths were reported from diphtheria from 1990-1999 in the former Soviet Union.

Tetanus (Lockjaw)

Tetanus is a severe, often fatal disease. The bacteria that cause tetanus are widely distributed in soil and street dust, are found in the waste of many animals, and are very resistant to heat and germ-killing cleaners. From 1922-1926, there were an estimated 1,314 cases of tetanus per year in the U.S. In the late 1940's, the tetanus vaccine was introduced, and tetanus became a disease that was officially counted and tracked by public health officials. In 2000, only 41 cases of tetanus were reported in the U.S.

People who get tetanus suffer from stiffness and spasms of the muscles. The larynx (throat) can close causing breathing and eating difficulties, muscles spasms can cause fractures (breaks) of the spine and long bones, and some people go into a coma, and die. **Approximately 20 percent of reported cases end in death.**

Tetanus in the U.S. is primarily a disease of adults, but unvaccinated children and infants of unvaccinated mothers are also at risk for tetanus and neonatal tetanus, respectively. From 1995-1997, 33 percent of reported cases of tetanus occurred among persons 60 years of age or older and 60 percent occurred in patients greater than 40 years of age. The National Health Interview Survey found that in 1995, only 36 percent of adults 65 or older had received a tetanus vaccination during the preceding 10 years.

Worldwide, tetanus in newborn infants continues to be a huge problem. Each year, **tetanus kills 300,000 newborns and 30,000 birth mothers who were not properly vaccinated.** Even though the number of reported cases is low, an increased number of tetanus cases in younger persons have been observed recently in the U.S. among intravenous drug users, particularly heroin users.

Tetanus is infectious, but not contagious, so unlike other vaccine-preventable diseases, immunization by members of the community will not protect others from the disease. Because tetanus bacteria are widespread in the environment, tetanus can only be prevented by immunization. If vaccination against tetanus were stopped, persons of all ages in the U.S. would be susceptible to this serious disease.

Mumps

Before mumps vaccine was introduced, mumps was a major cause of deafness in children, occurring in approximately 1 in 20,000 reported cases. Mumps is usually a mild viral disease. However, rare conditions such as swelling of the brain, nerves and spinal cord can lead to serious side effects such as paralysis, seizures, and fluid in the brain.

Serious side effects of mumps are more common among adults than children. Swelling of the testes is the most common side effect in males past the age of puberty, occurring in up to 20 percent to 50 percent of men who contract mumps. **An increase in miscarriages has been found among women who develop mumps during the first trimester of pregnancy.**

An estimated 212,000 cases of mumps occurred in the U.S. in 1964. After vaccine licensure in 1967, reports of mumps decreased rapidly. In 1986 and 1987, there was a resurgence of mumps with 12,848 cases reported in 1987. Since 1989, the incidence of mumps has declined, with 266 reported cases in 2001. This recent decrease is probably due to the fact that children have received a second dose of mumps vaccine (part of the two-dose schedule for measles, mumps, rubella or MMR) and the eventual development of immunity in those who did not gain protection after the first mumps vaccination.

We cannot let our guard down against mumps. A 2006 outbreak among college students, most of whom had received two doses of vaccine, led to over 5500 cases in 15 states. Mumps is highly communicable and it only takes a few unvaccinated to initiate transmission.

Source: CDC - Vaccines and Immunizations **http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm#intro**

Economic Value of Vaccines*

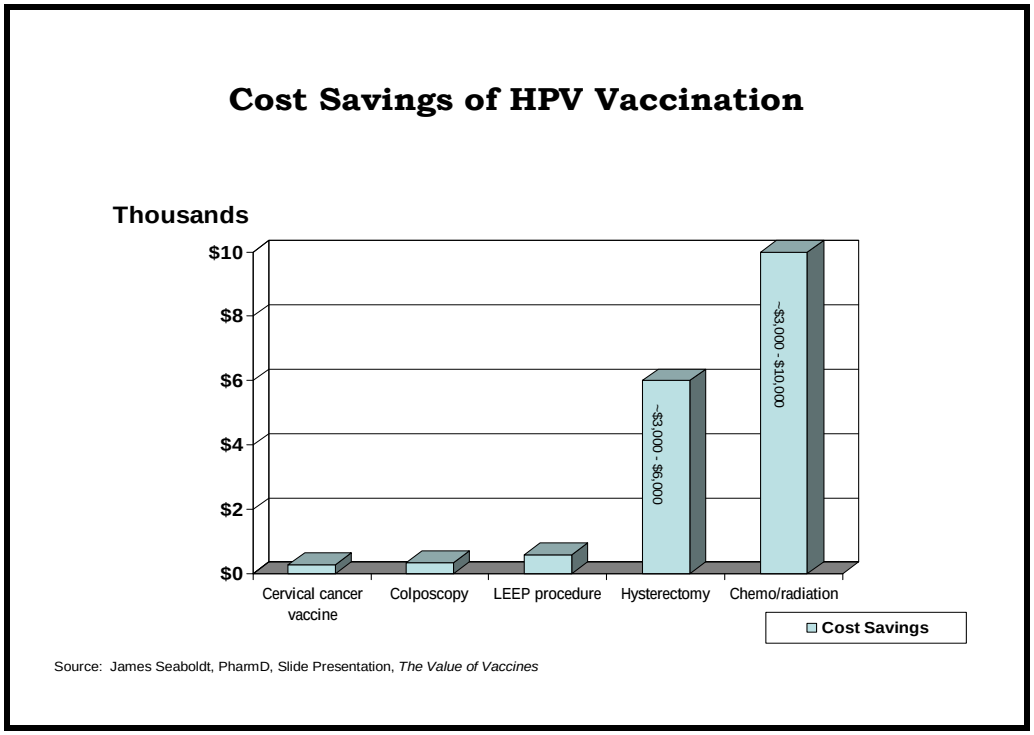
In addition to saving lives and improving the quality of life, immunization generates significant economic benefits. According to an extensive cost-benefit analysis by the CDC, every dollar spent on immunization saves $6.30 in direct medical costs, with an aggregate savings of $10.5 billion. When including indirect costs to society -- a measurement of losses due to missed work, death and disability as well as direct medical costs -- the CDC notes that every dollar spent on immunization saves $18.40, producing societal aggregate savings of $42 billion[1]. Various cost-benefit analyses produce similar measurements[2]

The diphtheria, tetanus, and pertussis (DTaP) vaccine is particularly cost effective. Each dollar spent on DTaP produces $8.50 of direct medical cost savings and $24 of societal savings[3]. More importantly, diphtheria immunizations alone prevent almost 13,000 deaths per year.

For every $1 spent	
DTaP saves	$27.00
MMR saves	$26.00
H. Influenza type b saves	$5.40
Perinatal Hep B saves	$14.70
Varicella saves	$5.40
Inactivated Polio (IPV) saves	$5.45

1. Ross Rapoport, "CDC: Immunizations High But Shot In Arm Still Needed," Cox News Service. 1 August 2003.
2. Zhou, et al, "Economic Evaluation of Routine Childhood Immunization with DTaP, Hib, IPV, MMR and Hep B Vaccines in the United States," Pediatric Academic Societies Conference, Seattle, Washington, May 2003.
3. Ibid.

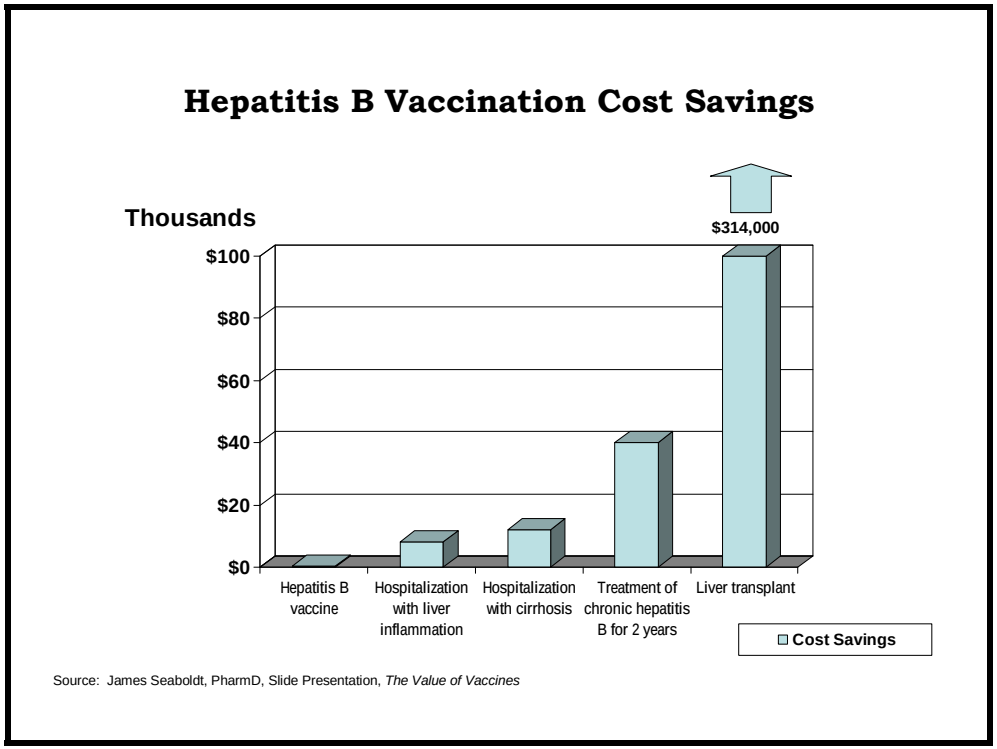
*Source – Every Child By Two **http://www.ecbt.org/advocates/economicvaluevaccines.cfm#_ednref3**



Human Papillomavirus (HPV) vaccine was licensed 2006. The vaccine is a 3-dose series given over a 6 month period. Data are not yet available yet on the impact the vaccine has on reducing the rate of cervical cancer caused by types 6, 11, 16 and 18 (types found in the vaccine).

HPV infection is believed to be the most common sexually transmitted infection in the U.S. An estimated 20 million persons are currently infected, and an estimated 6.2 million new HPV infections occur annually. HPV infection is common among adolescents and young adults. Prevalence among adolescent girls is as high as 64%. Up to 75% of new infections occur among persons 15-24 years of age. Modeling estimates suggest that more than 80% of sexually active women will have been infected by age 50*.

**Epidemiology and Prevention of Vaccine-Preventable Diseases 10th Edition, 2007.* U.S. Department of Health and Human Services, CDC, P.286.



The hepatitis B vaccine is a 3-dose series given over a 6 month period. The average cost of the 3 doses series is under $50 (~$15.79/dose).

Adverse Reactions Following Vaccination in Arizona

An adverse reaction is an untoward effect caused by a vaccine that is extraneous to the vaccine's primary purpose of producing immunity. Adverse reactions are also called vaccine side effects. A vaccine adverse event refers to **any** medical event that occurs following vaccination. An adverse event could be a true adverse reaction or just a coincidental event, with further research needed to distinguish between them.
Vaccine adverse reactions fall into three general categories; local, systemic, and allergic. Local reactions are generally the least severe and most frequent. Allergic reactions are the most severe and least frequent.

Source: *Epidemology and Prevention of Vaccine-Preventable Diseases*, Department of Health and Human Services, Centers for Disease Control and Prevention, p.15.

The Vaccine Adverse Event Reporting System (VAERS)

Introduction to VAERS

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. Additional scientific investigations are almost always required to properly validate signals from VAERS and establish a cause and effect relationship between a vaccine and an adverse event.

VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, VAERS has received over 123,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS can help to identify important new safety concerns.

The Vaccine Adverse Event Reporting System is a cooperative program for vaccine safety of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of US licensed vaccines.

This Web site provides a nationwide mechanism by which adverse events following immunization (AEFI) may be reported, analyzed and made available to the public. The VAERS Web site also provides a vehicle for disseminating vaccine safety-related information to parents/guardians, healthcare providers, vaccine manufacturers, state vaccine programs, and other constituencies.

When evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. VAERS is interested in all potential associations between vaccines and adverse events. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event.

Over ten million vaccinations per year are given to children less than one year old, usually between 2 months and 6 months of age. At this age, infants are at greatest risk for certain medical events, including high fevers, seizures, and sudden infant death syndrome (SIDS). Some infants will by coincidence experience such an event shortly after a vaccination.

These coincidences make it difficult to know whether a particular adverse event resulted from a concurrent condition or from a vaccination. Therefore, doctors and other vaccine providers are encouraged to report all adverse events following vaccinations, whether or not they believe that the vaccination was the cause.

VAERS data are derived from a passive surveillance system and represent unverified reports of health events, both minor and serious, that are reported after vaccination. In certain cases VAERS requests additional information from reporters, healthcare providers and other parties. The status, event description and medical codes associated with a report are subject to change upon receipt of such additional information.

When multiple reports of a single case or event are received, only the first report received is included in the publicly accessible dataset. Subsequent reports may contain additional or conflicting data, and there is no assurance that the data provided in the public dataset is the most accurate or current available. Such data

are subject to limitations of under-reporting, simultaneous administration of multiple vaccine antigens (making it difficult to know to which of the vaccines, if any, the event might be attributed), reporting bias, and lack of incidence rates in unvaccinated comparison groups. While some events reported to VAERS are truly caused by vaccines, others may be related to an underlying disease or condition, to medications being taken concurrently, or may occur by chance.

VAERS occasionally receives case reports from US manufacturers that were reported to their foreign subsidiaries. Under FDA regulations, if a manufacturer is notified of a foreign case report that describes an event that is both serious and unexpected (in other words, it does not appear in the product labeling), they are required to submit it to VAERS. It is important to realize that these case reports are of variable data quality and completeness, due to the many differences in country reporting practices and surveillance system quality. For this reason they are provided as separate files. In some media reports and on some web sites on the Internet, VAERS reports are presented as verified cases of vaccine deaths and injuries. Statements such as these misrepresent the nature of the VAERS surveillance system.

All narrative text taken from VAERS reports are coded and entered into the VAERS database using the Medical Dictionary for Regulatory Activities (MedDRA), which are key words representing medical condition(s) described in the case report.

For example, potential concerns raised by VAERS are investigated through a CDC project called the **Vaccine Safety Datalink** (VSD). VSD is a large-linked database and includes information on more than six million people, allowing for planned vaccine safety studies as well as timely investigations of hypotheses.

VAERS Reporting

Anyone can submit a VAERS report. Most reports are sent in by vaccine manufacturers (42%) and health care providers (30%). The rest are submitted by state immunization programs (12%), vaccine recipients or their parent/guardians (7%), and other sources (9%).

VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. Report such events even if you are unsure whether a vaccine caused them. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination.

A copy of the Reportable Events Table can be obtained by calling VAERS at 1-800-822-7967 or by downloading it from ***http://vaers.hhs.gov/pubs.htm****.*

Anybody can use a VAERS report form to report any adverse event. Pre-addressed postage paid report forms are available by calling VAERS at 1-800-822-7967, or download a printable copy of the VAERS form from the following Internet sites:

- The VAERS Web site at **http://vaers.hhs.gov/**
- The Food and Drug Administration's Web site at **http://www.fda.gov/cber/vaers/vaers.htm**
- The Centers for Disease Control and Prevention Web site at **http://www.cdc.gov/vaccines/default.htm**
  Instructions are included with the form. You may use a photocopy of the VAERS form to submit a report.

For more information:

- Send e-mail inquiries to **info@vaers.org**
- Visit the VAERS Web site at: **http://vaers.hhs.gov**
- Call the toll-free VAERS information line at (800) 822-7967
- Fax inquiries to the toll-free information fax line at (877) 721-0366

This information has been adapted from the VAERS website (**http://vaers.hhs.gov**).

2007* Arizona (Adverse Reaction) Data

***2007 Arizona VAERS data available 1/1/2007 through 10/31/2007 at time of this report.**

1. The current national or state system for reporting and collecting information regarding adverse effects of vaccines is done through the national Vaccine Adverse Events Reporting System (VAERS). VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, VAERS has received over 123,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS helps to identify any important new safety concerns.

2. Two hundred fifty-three adverse events were reported on individuals 2 months through 18 years of age in Arizona between 1/1/2007 through 10/31/2007. Arizona State Immunization Information System (ASIIS) data demonstrate that 2,191,145 vaccines were administered to this age group during the same time frame (1/1/07 – 10/31/07). Adverse reactions were recorded in less than 0.001% of all vaccinations in Arizona among children. A total of 439 vaccine adverse events were reported on all ages during this time period. Attachment A contains the actual VAERS Data for Arizona. The following is a breakdown of the 439 adverse events reported from Arizona.

Adverse Events by Age:

- 2 months through 18 years of age	253
- 19 through 64 years of age	106
- 65 through 98 years of age	44
- Age not reported	36

Adverse Events from Vaccines Administered By:

- Private	198
- Other	115
- Public	64
- Unknown	38
- Military	24

Adverse Events Vaccines Purchased with:

- Private funds	142
- Unknown funds	102
- Other funds	87
- Public funds (county, state, federal)	84
- Military funds	24

The 6 most frequently reported adverse events during 2007 in Arizona were: 1) Drug ineffective; 2) Redness at the injection site; 3) Weakness; 4) Pain at injection site; 5) Itching; and 6) Joint pain. Attachment A provides a line listing of the adverse events reported.

3. The entities health professionals contact when the professional suspects a person has had an adverse reaction to a vaccine include:

a. Public health facilities report vaccine adverse events to the state immunization program or directly to VAERS. The state immunization program reports all vaccine adverse events they receive to VAERS.

b. Private and military providers report vaccine adverse events directly to VAERS.

VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. Clinically significant adverse events should be reported even if the health professional is unsure whether a vaccine caused the event.

The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine. Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination. A copy of the Reportable Events Table can be obtained by calling VAERS at 1-800-822-7967 or by downloading it from **http://vaers.hhs.gov/pubs.htm**

4. The information provided when an adverse reaction occurs is reported to VAERS is found on the VAERS reporting form (attached). The information includes:

a. Patient name, address and telephone number
b. Name of person administering the vaccine; Name of the Responsible Physician; Facility Name/Address/Telephone number
c. Name, address, telephone number and relation to the patient of the person completing the form
    1) Vaccine Provider
    2) Manufacturer
    3) Patient/Parent
    4) Other
d. Name of state reporting the information
e. County where vaccine was administered
f. Patient date of birth, age, and sex
g. Date form was completed
h. Description of the adverse event(s) and treatment, if any
    1) Check all appropriate
    2) Patient died
    3) Life threatening illness
    4) Required emergency room/doctor visit
    5) Required hospitalization - number of days
    6) Resulted in prolongation of hospitalization
    7) Resulted in permanent disability
    8) None of the above
j. Patient recovered
    1) Yes
    2) No
    3) Unknown
k. Date of vaccination
l. Date of Adverse event onset
m. Relevant diagnostic tests/laboratory data
n. Name, manufacturer, lot number, route/site administered, number of previous doses and date given of all vaccines administered
o. Vaccinated at:
    1) Private doctor's office/hospital
    2) Public health clinic/hospital

3) Military clinic/hospital
4) Other/unknown

p. Vaccine purchased with
1) Private funds
2) Public funds
3) Military funds
4) Other/unknown

q. Other medications
r. Illness at time of vaccination (specify)
s. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)
t. Have you ever reported this adverse event previously?
1) No
2) To doctor
3) To health department
4) To manufacturer

u. Adverse event following prior vaccination (check all applicable, specify)
1) In patient - adverse event, onset age, type vaccine, dose number in series
2) In brother or sister - adverse event, onset age, type vaccine, dose number in series

v. For children under 5 years of age only:
1) birth weight
2) number of brothers and sisters

5. How other states collect and disseminate information related to vaccine adverse events:

All fifty states, Indian Health Service, American Samoa, Guam, the Marshall Islands, Micronesia, the Northern Mariana Islands, Palau, Puerto Rico and the Virgin Islands collect and report information related to vaccine adverse effects of vaccines to VAERS. No state or territory has its own internal vaccine adverse event reporting system.

6. Vaccines recommended to be administered in Arizona:

All vaccines administered in Arizona are vaccines that have been recommended by the CDC Advisory Committee on Immunization Practices (ACIP). ACIP consists of 15 experts in fields associated with

immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population. Recommendations include appropriate ages for vaccine administration, the number of doses, dosing intervals, and precautions and contraindications (temporary or permanent conditions in an individual that could cause an adverse reaction to a vaccine). **The ACIP is the only entity in the federal government that makes such recommendations.**

The overall goals of the ACIP are to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products.

The current ACIP members:

Dale L. Morse L., M.D. - Chairman
Director, Office of Science and Public Health
New York State Department of Health

Larry K. Pickering, M.D. – Executive Secretary
Senior Advisor to the Director
National Center for Immunization & Respiratory Diseases
Centers for Disease Control and Prevention

Carol J. Baker, M.D.
Professor of Pediatrics
Molecular Virology and Microbiology
Baylor College of Medicine

Robert L. Beck, J.D.
Consumer Representative

Lance Chilton, M.D.
General Pediatrics and Adolescent Medicine

Young Children's Health Center
Professor, Department of Pediatrics
University of New Mexico School of Medicine

Paul Cieslak, M.D.
Medical Director, Immunization Program and
Program Manager, Acute & Communicable Disease Prevention
Oregon Public Health Division

Janet Englund, M.D.
Associate Professor of Pediatrics, University of Washington
Clinical Associate, Fred Hutchinson Cancer Research Center
Division of Infectious Disease, Immunology and Rheumatology
Children's Hospital and Regional Medical Center

Franklyn Judson, M.D.
Professor, Departments of Medicine and Preventive Medicine & Biometrics
University of Colorado at Denver and Health Sciences Center

Susan Lett, M.D., M.P.H.
Medical Director, Immunization Program
Division of Epidemiology and Immunization
Massachusetts Department of Public Health

Tracy Lieu, M.D., M.P.H.
Professor and Director, Center for Child Health Care Studies
Department of Ambulatory Care and Prevention
Harvard Pilgrim Health Care and Harvard Medical School

Julia Morita, M.D.
Medical Director, Immunization Program
Chicago Department of Public Health

Kathleen Neuzil, M.D., M.P.H.
Senior Clinical Advisor, PATH
Clinical Associate Professor of Medicine,
University of Washington

Patricia Stinchfield, NP
Director, Pediatric Infectious Disease & Immunology Infection Control
Children's Hospitals and Clinics of Minnesota

Ciro Valent Sumaya, M.D., M.P.H. & T.M.
Founding Dean, School of Rural Public Health and
Cox Endowed Chair in Medicine
Texas A&M University System Health Science Center

Ex Officio Members

Centers for Medicare and Medicaid Services (CMS)
Department of Defense (DOD)
Department of Veterans Affairs (DVA)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Vaccine Program Office (NVPO)
National Institutes of Health (NIH)

Liaison Representatives

American Academy of Family Physicians (AAFP)
American Academy of Pediatrics (AAP)
American College Health Association (ACHA)
American College of Obstetricians and Gynecologists (ACOG)
American College of Physicians (ACP)
American Geriatrics Society (AGS)
America's Health Insurance Plans (AHIP)
American Medical Association (AMA)

American Osteopathic Association (AOA)
American Pharmacists Association (APhA)
Association for Prevention Teaching and Research (APTR)
Biotechnology Industry Organization (BIO)
Canadian National Advisory Committee on Immunization (NACI)
Department of Health, United Kingdom
Healthcare Infection Control Practices Advisory Committee (HICPAC)
Infectious Diseases Society of America (IDSA)
National Association of County and City Health Officials (NACCHO)
National Foundation for Infectious Diseases (NFID)
National Immunization Council and Child Health Program, Mexico (NIACCHO)
National Medical Association (NMA)
National Vaccine Advisory Committee (NVAC)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Society for Adolescent Medicine (SAM)
Society for Healthcare Epidemiology of America (SHEA)

The ACIP recommended vaccines administered in Arizona by public, private and military providers:

DTaP	Diphtheria, tetanus, acellular pertussis
DT	Diphtheria tetanus
DTaP/Hib	Diphtheria, tetanus, acellular pertussis/*Haemophilus influenzae* type b
DTaP/IPV/Hep B	Diphtheria, tetanus, acellular pertussis/ Inactive Polio Vaccine/Hepatitis B
Hib	Hepatitis B
Hep A	Hepatitis A
Hep B	Hepatitis B
Hep A/Hep B	Hepatitis A/Hepatitis B
Hep B/Hib	Hepatitis B/*Haemophilus influenzae* type b
HPV	Human Papilloma Virus
Flu	Influenza
JE-Vax	Japanese encephalitis
MMR	Measles/Mumps/Rubella
MMRV	Measles/Mumps/Rubella/Varicella

Attenuvax	Measles
Mumpsvax	Mumps
Meruvax	Rubella
Mening	Meningococcal
Pneumo	Pneumococcal
Polio	Polio
Rabies	Rabies
Rota	Rotavirus
Td	Tetanus diphtheria
Tdap	Tetanus diphtheria acellular pertussis
TT	Tetanus Toxoid
Typhoid	Typhoid
VAR	Varicella
Vaccinia	Smallpox
Yellow Fever	Yellow Fever
Zoster	Shingles

Vaccines in **green** are purchased with county, state, federal and private monies. The vaccine in **red** (Vaccinia/Smallpox) is available to the military only. Vaccines in **black** are administered for special circumstances and are not routine. The types and amounts of vaccine purchased with private funds is propriety information and therefore, unknown. The types and amount of vaccines purchased by private health professionals also depend on the type of medical practice – pediatrics, family practice, geriatrics, travel, etc. It can be assumed that:

- Typhoid, Yellow Fever and Japanese encephalitis vaccines are purchased with county health department (public) and private funds and administered for a fee by public and private providers;
- Rabies vaccine is purchased with state and county health department (public) and private funds. The economic status of the patient would likely determine payment.
- Single antigen vaccines – Meruvax (measles), Mumpsvax (mumps), Attenuvax (rubella), and TT (Tetanus Toxoid) are not readily available and are not routinely administered. If these vaccines were available, they would be purchased with private or military funding only.

For further information regarding adverse events to vaccines, vaccines in general, vaccine funding, or other vaccine-related information, please contact Kathy Fredrickson, MS, MPH, Office Chief, Arizona Immunization Program Office by telephone at (602) 364-3630 or by email at **Fredrik@azdhs.gov**

Attachment A

Arizona 2007 VAERS Data

Age in Years	Gender	Primary Complaint or Reaction
0	F	Crying
0	F	Agitation
0	F	Flushing
0.2	M	Redness at Injection site
0.2	M	Discomfort
0.2	F	Redness at injection site
0.2	F	Contusion
0.2	M	Injection site vesicles
0.2	F	Itching
0.2	F	Face swelling
0.2	F	Unknown
0.2	F	Injection site swelling
0.2	F	Chills
0.2	F	Dehydration
0.2	M	Decreased sensation
0.2	F	Feeling hot
0.3	F	Weakness
0.3	F	Dizziness
0.3	F	Blood potassium increased
0.3	M	Acute tonsillitis
0.3	M	Blood calcium normal
0.3	M	Blood electrolytes decreased
0.3	F	Feeling hot
0.4	F	Rash
0.4	F	Redness at injection site
0.4	F	Irritability
0.4	F	Injection site warmth
0.4	F	Decreased appetite
0.4	F	Injection site nodule
0.4	F	Redness at injection site

0.5	F	Redness at injection site
0.5	U	Anorexia
0.5	F	Redness at injection site
0.5	F	Itching
0.5	M	Pain
0.5	M	Cough
0.6	F	Redness at injection site
0.6	F	Hair loss
0.6	M	Itching rash
0.7	M	Anxiety
0.8	U	Redness at injection site
0.8	U	Pain
0.8	M	Dizziness
0.9	F	Redness at injection site
1	F	Pain
1	M	Joint pain
1	M	Itching
1	M	Redness at injection site
1	F	Redness at injection site
1	F	Blood culture negative
1	M	Blood culture positive
1	F	Redness at injection site
1	F	Medication error
1	F	Amnesia
1	F	Contusion
1	F	Skin infection
1	F	Medication error
1	M	Redness at injection site
1	F	Hair loss
1	F	Speech change
1	F	Blister
1	M	Dizziness
1	M	Redness at injection site
1.1	F	Skin infection
1.1	F	Nausea
1.1	F	Redness at injection site
1.1	F	Nausea

1.1	F	Redness at injection site
1.1	F	Redness at injection site
1.1	M	Insomnia
1.2	M	Choking
1.2	F	Chills
1.2	F	Vaccination failure
1.2	F	Herpes zoster
1.3	F	Weakness
1.3	M	Neutropenia
1.3	M	Blood calcium decreased
1.3	M	Itching
1.3	M	Redness at injection site
1.3	M	Weakness
1.3	F	Redness at injection site at injection site
1.3	M	Fever
1.3	F	Chills
1.4	F	Blister
1.5	F	Redness at injection site
1.5	F	Feeling hot
1.5	M	Injection site swelling
1.6	M	Basedow's disease
1.8	F	Joint pain
1.8	M	Injection site swelling
1.9	F	Injection site pain
2	F	Chills
2	M	Malaise
2	F	Malaise
2	F	Abdominal pain
2	F	Redness at injection site
2	F	Redness at injection site
3	F	Redness at injection site
3	F	Screaming
3	M	Diarrhrea
3	F	Weakness
3	M	Redness at injection site
3	M	Breast pain
3	F	Redness at injection site

3	F	Muscle spasms
4	F	Blister
4	F	Weakness
4	F	Blood culture positive
4	F	Herpes zoster
4	M	Medication error
4	F	Injection site warmth
4	F	Loss of consciousness
4	M	Redness at injection site
4	F	Redness at injection site
4	F	Medication error
4	F	Redness at injection site
4	F	Pain
4	F	Chills
4	F	Convulsion
4	F	Muscle weakness
4	F	Speech change
4	M	Skin infection
4	M	Difficulty in walking
4	F	Redness at injection site
5	M	Blood albumin increased
5	F	Cardiomegaly
5	M	Skin infection
5	M	Anion gap (pH change)
5	F	Skin infection
5	F	Discomfort
5	M	Redness at injection site
5	M	Decreased appetite
5	M	Redness at injection site
5	F	Rash
5	F	Chills
5	M	Redness at injection site
5	M	Chills
5	F	Chills
5	F	Unavailable event
5	F	Feeling hot
6	F	Vertigo

6	M	Diarrhrea
6	M	Anorexia
6	M	Diarrhrea
6	M	Rash
7	F	Nausea
7	F	Feeling hot
7	M	Feeling hot
8	F	Atrial tachycardia
8	F	Speech change
8	M	Shortness of breath
8	M	Joint pain
8	U	Application site warmth
9	F	Redness at injection site
9	M	Croup infection
9	F	Joint pain
9	M	Crying
9	M	Redness at injection site
11	F	Abdominal pain
11	F	Itching
12	F	Abdominal pain
12	F	Pregnancy complications
12	F	Pregnancy complications
12	F	Blood pressure decreased
12	F	Short-term vision problem
12	M	Diarrhrea
12	M	Short -term hearing problem
13	F	Varicella
13	M	Abnormal sensation in eye
13	F	Rash generalized
13	F	Pain in extremity
13.5	M	Redness at injection site
14	M	Redness at injection site
14	F	Herpes zoster
14	M	Redness at injection site
14	F	Itching
15	F	Rash generalized
16	F	Chest X-ray normal

16	F	Dizziness
16	F	Back pain
16	M	Hypo-aesthesia
16	F	Redness at injection site
17	M	Redness at injection site
17	F	Weakness
17	F	Contusion
17	F	Face edema
17	F	Dizziness
17	F	Cough
18	M	Skin discoloration
18	M	Pain
18	F	Culture urine negative
18	F	Anorexia
18	F	Abdominal X-ray
18	F	Chest pain
18	F	Redness at injection site
18	M	Contusion
18	M	Hard lump at injection site
18	M	Chest discomfort
18	M	Tremor
18	M	Anxiety
19	M	Redness at injection site
19	M	Weakness
19	M	Herpes zoster
19	M	Herpes zoster
19	M	Joint pain
20	F	Joint pain
20	M	Redness at injection site
20	F	Bedridden
20	F	Anaphylactic reaction
20	M	Convulsion
20	M	Body temperature
20	F	Multiple sclerosis
21	F	Redness at injection site
21	F	Injection site skin infection
21	M	Joint pain

21	M	Redness at injection site
22	F	Febrile convulsion
22	F	Fainting
23	F	Flushing
23	F	Itching rash
23	F	Full blood count
24	F	Fever
25	F	Blister
25	F	Redness at injection site
25	M	Redness at injection site
25	M	Injection site skin infection
26	M	Drug ineffective
26	M	Joint pain
26	F	Speech change
26	F	Swollen lymph glands
26	F	Ear pain
27	M	Gait disturbance
27	F	Pain
27	F	Chest discomfort
27	F	Medication error
27	M	Cyanosis
28	F	Blister
29	M	Blister
29	F	Injection site warmth
29	F	Itching rash
30	F	Unknown
30	F	Pallor
30	F	Redness at injection site
30	U	Drug ineffective
30	U	Drug ineffective
30	M	Drug ineffective
30	F	Hepatitis B surface antigen positive
31	M	Hepatitis B antigen positive
31	F	Joint pain
32	U	Hepatitis B surface antigen positive
32	U	Hepatitis B surface antigen positive
32	U	Hepatitis B surface antigen positive

32	F	Migraine
32	U	Hepatitis B surface antigen positive
32	U	Dialysis
33	U	Dialysis
33	F	Drug ineffective
34	F	Drug ineffective
34	F	Drug ineffective
34	F	Drug ineffective
34	M	Drug ineffective
34	F	Drug ineffective
35	M	Shortness of breath
35	M	Incorrect dose administered
35	F	Joint pain
35	F	Convulsion
35	F	Therapeutic response decreased
35	F	Partial loss of sensation at site
36	F	Drug ineffective
37	U	Haemodialysis
37	U	Haemodialysis
37	F	Redness at injection site
38	U	Drug ineffective
38	U	Drug ineffective
38	U	Drug ineffective
38	F	Blood cholesterol increased
39	F	Hepatitis B antigen positive
39	M	Drug ineffective
40	F	Blood pressure increased
40	F	Laboratory test abnormal
40	F	Dizziness
40	U	Drug ineffective
40	U	Drug ineffective
40	U	Drug ineffective
41	U	Drug ineffective
41	U	Drug ineffective
41	F	Drug ineffective
42	M	Hepatitis B surface antigen positive
42	M	Hepatitis B antibody negative

42	F	Listless
42	M	Diabetic end stage renal disease
42	M	Diabetic end stage renal disease
42	M	Drug ineffective
42	F	Drug ineffective
43	M	Rash
43	F	Redness at injection site
43	U	Developmental delay
43	F	Drug ineffective
44	F	Drug ineffective
44	U	Hepatitis C
44	U	Hypersensitivity
44	F	Abdominal pain
45	F	Drug ineffective
46	U	Drug ineffective
46	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
47	U	Drug ineffective
48	U	Drug ineffective
48	U	Drug ineffective
49	U	Drug ineffective
49	U	Drug ineffective
49	U	Drug ineffective
49	M	Drug ineffective
49	U	Drug ineffective
49	F	Drug ineffective
50	F	Prophylaxis
50	F	Muscle weakness
50	U	Prophylaxis
50	U	Therapeutic response decreased
51	F	Injection site irritation
51	F	Itching
51	U	Injection site bleeding

52	F	Hepatitis B antibody
52	F	Dizziness
52	F	Therapy non-responder
52	M	Drug ineffective
52	F	Abdominal pain
52	M	Hepatitis B antigen positive
53	M	Redness at injection site
53	M	Hepatitis B antigen positive
53	F	Drug ineffective
53	F	Incorrect dose administered
53	F	Incorrect dose administered
54	M	Redness at injection site
54	F	Hepatitis B surface antigen
54	F	Hepatitis B surface antigen
54	M	Abdominal discomfort
55	F	Redness at injection site at injection site
56	M	Decrease in taste
56	F	Hepatitis B antigen positive
56	F	Drug ineffective
56	F	Drug ineffective
56	F	Hepatitis B surface antigen positive
56	U	Hepatitis B antigen positive
57	F	Headache
57	F	Hepatitis B antibody negative
57	F	Itching
57	F	Feeling abnormal
58	F	Hepatitis B antibody
58	U	Hepatitis B antibody
58	F	Rash
58	U	Hepatitis B surface antigen
58	M	Diarrhrea
58	F	Decrease in taste
58	M	Hepatitis B surface antigen
59	M	Chills
59	M	Hepatitis B antibody
59	F	Hepatitis B antibody
59	M	Drug ineffective

59	F	Rash
60	M	Weakness
60	M	Injection site pain
60	F	Injury
61	U	Developmental delay
62	M	Autism
62	M	Weakness
62	F	Joint pain
62	F	Weakness
62	F	Injection site reaction
62	F	Oral numbness
63	M	Joint pain
63	F	Chest discomfort
64	F	Blood test
65	M	Cough
65	F	Computerised tomogram normal
65	F	Chest X-ray abnormal
65	F	Fever
65	F	Itching rash
65	F	Weakness
65	M	Abnormal feces
66	M	Redness at injection site
67	M	Weakness
68	F	Injection site infection
68	M	Redness at injection site
68	M	Feeling hot
68	F	Fall
68	F	Redness at injection site
69	M	Redness at injection site
69	F	Swelling
70	F	Dizziness
70	F	Redness at injection site
70	F	Back pain
71	M	Redness at injection site
71	F	Skin infection
71	M	Redness at injection site
72	M	Injection site pain

72	F	Redness at injection site
74	M	Redness at injection site
74	F	Weakness
75	F	Redness at injection site
75	M	Fever
75	F	Redness at injection site
77	F	Underarm pain
78	M	Redness at injection site
78	M	Varicella (chickenpox)
78	F	Redness at injection site
79	F	Redness at injection site
79	M	Injection site rash
80	F	Nausea
80	M	Unavailable event
80	M	Rash
81	F	Joint pain
84	F	Chest pain
97	F	Chills
Unknown	U	Skin rash
Unknown	M	Injection site pain
Unknown	F	Weakness
Unknown	F	Flank pain
Unknown	M	Incorrect drug dosage administered
Unknown	F	Redness at injection site
Unknown	M	Demyelination
Unknown	F	Anxiety
Unknown	F	Atrial hypertrophy
Unknown	F	Body temperature increased
Unknown	F	Herpes zoster
Unknown	F	Anaphylactic reaction
Unknown	M	Redness at injection site
Unknown	F	Fever
Unknown	F	Abdominal pain
Unknown	F	Convulsion
Unknown	M	Feces discoloured
Unknown	U	Diarrhrea
Unknown	M	Bloody diarrhrea

Unknown	M	Weakness
Unknown	M	Joint pain